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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,140	01/19/2001	Donald Michael Black	5950-01-CA	3004

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EXAMINER
MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
3738	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,140	Applicant(s) BLACK, DONALD MICHAEL	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9,12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Arguments

1. Applicant's arguments with respect to claims 1-10 have been considered but are not persuasive.

2. Regarding claims 1-3 as rejected under 35 U.S.C. 102(e) as being anticipated by Seed et al. US PN 5,861,399, Applicant contends that Seed et al. does not teach administration of a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol, but rather discloses a combination of treatments (drugs and diet). Examiner acknowledges the disclosure of combining diet, but the claims do not require the exclusion of dietary restrictions. Furthermore, Seed et al. clearly discloses "an amount effective to cause an aggressive lowering of cholesterol" as described in column 7 wherein LDL of 115 mg/dl is taught to be reduced to average levels of 42 mg/dl after 1 year.

3. Regarding claims 1-4 and 9-10 as rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney et al. US PN 6,180,660 in view of Jeevanandam et al. US PN 5,957,916, applicant contends that Whitney et al. requires the patients to have no history of clinically evident coronary heart disease prior to initial examination and that the procedure is for prevention of a first occurrence of a major cardiovascular event, i.e. primary prevention. The Examiner agrees that Whitney et al. discloses those two points, but the overall scope of the disclosure and trials conducted extend further. For example, lines 29-44 of column 5 describe awareness of the "trend to treat coronary heart disease aggressively before a myocardial infarction has occurred" and using

"aggressive pharmacological intervention". Even though patients are described in the abstract as not having clinical evidence of coronary artery heart disease (clinical evidence is described in lines 34-44 of col. 6 as prior history of myocardial infarction, angina, or claudication), some may have suffered or did suffer from coronary artery disease (claim 1). The patients selected for the trial had elevated levels of LDL cholesterol up to 190 mg/dl (lines 44-52 of col. 5) suggesting a certain degree of coronary artery disease. Furthermore, Whitney et al. provides clear evidence in lines 1-37 of column 7 that participants, that were treated for extended periods of time, were withdrawn from the program if measured LDL cholesterol levels were greater than 195 mg/dl on **successive visits following titration**. Note that "visits" occurred every 6 weeks. Therefore at least 12 weeks of treatment (titration) was provided to patients that were later clinically determined (by measuring LDL cholesterol levels) to not meet requirements and were then withdrawn from the study. Furthermore, LDL cholesterol levels above 195 mg/dl would strongly suggest accumulation of cholesterol in the arteries (coronary artery disease) as known to those of ordinary skill in the field of cardiovascular doctors.

With further discussion on "patients sufferering from coronary artery disease", Applicant's disclosure has not fully described what is encompassed by this limitation. Lines 18-25 of page 7 describe coronary artery disease as either asymptomatic or mildly to moderately symptomatic and LDL cholesterols levels greater than or equal to 130 mg/dL. Therefore the high levels of LDL cholesterol (190 mg/dL to greater than 195

mg/dL) disclosed in Whitney et al. fulfills the limitation "patients sufferering from coronary artery disease".

4. With regard to claims 1-6 as rejected under 35 U.S.C. 103(a) as being unpatentable over Bocan et al. WO 97/16184 in view of Jeevanandam et al. US PN 5,957,916, Applicant contends Bocan et al. lacks express disclosure of performing the method to prevent or delay catheter based revascularization. Examiner respectfully disagrees. Bocan et al. discloses all elements of claims 1-6 as described in the rejection, except for "catheter-based revascularization". Lines 8-12 of page 5 of Bocan describes using HMG-CoA reductase inhibitors in patients with coronary artery disease without the requirement for siginificant regression of the atherosclerotic lesions." In other words, using drug therapy as an alternative to past treatment methods of atherosclerosis or coronary artery disease. Jeevanandam was provided to teach that it is well known to treat these diseases with a catheter based revascularization procedure such as angioplasty or stenting.

5. With regard to claims 1,7, and 8 as rejected under 35 U.S.C. 103(a) as being unpatentable over Bisgaier et al. US PN 5,648,387 in view of Jeevanandam et al. US PN 5,957,916, Applicant contends that Bisgaier does not focus on LDL lowering and lacks express disclosure of preventing or delaying catheter based revascularization, and should therefore be withdrawn. The Examiner disagrees. Bisgaier teaches LDL lowering for treatment of restenosis, coronary heart disease, and other vascular

disorders. Jeevanandam was provided to teach that it is well known to treat these diseases with a catheter based revascularization procedure such as angioplasty or stenting

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Seed et al. US PN 5,861,399.

See line 62 of col. 2 through line 20 of col. 3.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-4 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney et al. US PN 6,180,660 in view of Jeevanandam et al. US PN 5,957,916.

Whitney et al. discloses in lines 17-43 of col. 1, lines 8-13 of col. 2, 45-51 of col. 4, lines 27-29 of col. 3, Example 1 in col. 5-6, and lines 1-37 of col. 7 a method of administering cholesterol lowering drugs such as atorvastatin or fibrates to prevent or delay the need for coronary revascularization procedures. Whitney et al. lacks the express written disclosure that the coronary revascularization procedure to be prevented or delayed is catheter based. Jeevanandam et al. teaches in the abstract that is well known in the art that revascularization procedures are catheter based.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Whitney et al. by preventing a catheter based revascularization procedure as taught by Jeevandam et al.

10. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bocan WO 97/16184 in view of Jeevanandam et al. US PN 5,957,916.

Bocan discloses in see lines 12-25 of page 3 and lines 1-12 of page 5 a method of delaying or preventing the need for revascularization in patients suffering from coronary artery by administering 5-80 mg of atorvastatin per day. Bocan discloses all limitations of claims 1-6 but lacks the express disclosure of performing the method to prevent or delay a revascularization procedure that is catheter based. Jeevanandam et al. teaches in abstract that is well known in the art that revascularization procedures are catheter based.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Bocan by preventing a catheter based revascularization procedure as taught by Jeevandam et al.

11. Claims 1, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisgaier et al. US PN 5,648,387 in view of Jeevanandam et al. US PN 5,957,916.

Bisgaier discloses in lines 5-12 of col. 1, lines 26-35 of col. 2, and lines 35-62 of col. 6 a method of treating patients with coronary artery disease by administering effective amounts of cholesterol lowering drugs rather than other therapies. Bisgaier et al. discloses all elements of claims 1, 7, and 8 but lacks the express disclosure of preventing or delaying a catheter based revascularization. However, Jeevanandam et al. teachesin lines 20-33 of col. 1 that vascular diseases are well-known in the art to be treated with catheter based revascularization.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Bocan et al. by preventing a catheter based revascularization procedure as taught by Jeevandam et al.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM
April 4, 2003

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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